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NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL (NAFDAC)

PHARMACOVIGILANCE (PV) DIRECTORATE

POST-MARKET CLINICAL FOLLOW UP GUIDELINES FOR MEDICAL DEVICES AND IN VITRO DIAGNOSTICS

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ACRONYMS

AE	Adverse Event
GHTF	Global Harmonization Task Force
IMDRF	International Medical Devices Regulators Forum
ISO	International Organization for Standards
NPC	National Pharmacovigilance Centre
NAFDAC	National Agency for Food and Drug Administration and Control
SSCP	Summary of Safety and Clinical Performance
CE	European Conformity
NRA	National Regulatory Authority
CA	Conformity Assessment
CAPA	Corrective and Preventive Action
CER	Clinical Evaluation Report
EUMDR	EU Medical Devices Regulations
GSPR	General Safety and Performance Requirements
IVD Devices	In Vitro Diagnostic Devices
PRRC	Person Responsible for Regulatory Compliance
PMS	Post Market Surveillance
UDI	Unique Device Identifier
MAH	Marketing Authorization Holder
PMCF	Post-market Clinical Follow-up
MDCEWG	Medical Devices Clinical Evaluation Working Group
MDCG	European Medical Devices Coordination Group

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1.0 INTRODUCTION

The National Agency for Food and Drug Administration and Control (NAFDAC) Act, Cap N1, LFN 2004 empowers the Agency to control and regulate the manufacture, importation, distribution, advertisement, sale and use of its regulated products. This mandate requires that the Agency ensures the quality, safety and efficacy of all regulated products. The Agency, therefore, has developed NAFDAC Medical Devices and In Vitro Diagnostics Regulations, 2024, which stipulate the minimum standards that manufacturers are required to adhere to ensure the quality and safety of medical devices and in vitro diagnostic devices.

These guidelines are intended to help all stakeholders comply with the provisions of the NAFDAC Medical Devices, IVDs and Related Products Regulations, 2026, as it relates to Vigilance i.e. adverse events reporting and post-market clinical follow-up.

This document is to be used in conjunction with other existing relevant vigilance statutes in the country, all WHO Global Model Regulatory Framework for Medical devices, including In Vitro Diagnostics Medical Devices, as well as other related International Guidelines such as GHTF, IMDRF with the relevant annexures that have been adopted by the Agency including all applicable updates and revisions. The guidelines outlined below are to be considered as general guides, and they may be adapted to meet individual needs, provided all stakeholders comply with the regulatory objectives as they relate to post-market clinical follow-up.

All stakeholders are encouraged to send their comments to the Agency during the use of these guidelines to improve future editions.

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2.0 Scope and Objectives

These guidelines are intended to:

- Assist manufacturers of medical devices registered for use in Nigeria on the design, implementation and appropriate use of Post Market Clinical Follow-up studies. This document provides required guidance in relation to:
 - i. the conditions that may necessitate a PMCF study.
 - ii. the objectives of PMCF Studies.
 - iii. the design and implementation of PMCF studies; and
 - iv. The Relevance of Information from PMCF studies.

These guidelines apply to medical devices, IVDs and related products whose authorization to market or distribute includes requirements for active safety monitoring. The products include but are not limited to:

- All Medical Devices, IVDs and Related Products registered for use and placed on the market in Nigeria regardless of their risk class
- Legacy Devices: Devices that were on the market before the NAFDAC Medical Devices Regulation took effect must comply with reporting requirements.
- Investigational Medical Devices

The Agency may also require a Manufacturer or Marketing Authorization Holder, to adhere to these guidelines where the Agency identifies safety concerns during post-marketing surveillance. This does not discharge the Manufacturer or Marketing Authorization Holder of responsibility to monitor the safety of all its products through the established Vigilance Structure required by the Agency.

3.0 Legal and Regulatory Basis

This document is guided by:

- NAFDAC Act CAP N1 LFN 2024
- NAFDAC Medical Devices Regulations, 2026
- WHO Global Model Regulatory Framework for Medical devices including In Vitro Diagnostics Devices

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- GHTF and IMDRF Principles
- MDCG 2007 & MDCG 2008
- MDCG 2022-21

4.0 DEFINITIONS

4.1 Investigational Medical Device:

A Medical device that is being assessed for safety or performance in a clinical investigation.

Note: This includes medical devices already on the market that are being evaluated for new intended uses, new populations, new materials or design changes

4.2 Adverse Event

Any untoward or unintended medical occurrence in a patient, user or other person in relation to a medical device.

4.3 Serious Adverse Event (SAE)

An adverse event that

- a) led to a death,
- b) led to a serious deterioration in the health of the subject that:
 - 1) resulted in a life-threatening illness or injury,
 - 2) resulted in a permanent impairment of body structure or a body function,
 - 3) required in-patient hospitalization or prolongation of existing hospitalization,
 - 4) resulted in medical or surgical intervention to prevent permanent impairment to body structure or a body function.
- c) led to foetal distress, foetal death or a congenital abnormality or birth defect.

4.4 Serious Adverse Device Effect (SADE):

A SAE that is related, with a causal or reasonably possible relationship, to the use of: the Medical Device under investigation, the Medical Device comparator (e.g. a licensed Medical Device used as a reference in the study), or Investigational study procedures (e.g. Medical Device set-up)

4.5 Device User Facility:

A hospital, Clinic, diagnostic centre, laboratory, or laboratory that utilizes medical devices

4.6 Adverse Device Effect (ADE):

An Adverse event related to the use of an investigational medical device.

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This includes any adverse event resulting from insufficiencies or inadequacies in the instructions for use, the deployment, the implantation, the installation, the operation, or any malfunction of the investigational medical device.

This includes any event that is a result of a use error or intentional abnormal use of the investigational medical device.

4.7 Device Authorization Date”: Date device was granted marketing authorization status in Nigeria

4.8 Legacy Devices: Devices registered in Nigeria before the NAFDAC Medical devices and In vitro diagnostics regulations became applicable

4.9 Leading device: The “leading device” in a group of devices covered by the same PSUR corresponds to the highest risk class device. In the case when there are several devices with the same risk classification, the manufacturer should assign a leading device

4.10 Post-Market Clinical Follow-up (PMCF) is a proactive process to collect and analyze clinical data to monitor the safety and performance of a medical device once it is on the market. It involves systematic collection of data to confirm the ongoing clinical benefits, to detect potential risks, and to identify the need for further regulatory actions such as design changes or labelling updates, etc.

4.11 Clinical data: Safety, clinical performance and/or effectiveness information that is generated from the clinical use of a medical device.

4.12 Clinical evaluation: A set of ongoing activities that use scientifically sound methods for the assessment and analysis of clinical data to verify the safety, clinical performance and/or effectiveness of the medical device when used as intended by the manufacturer.

4.13 Clinical evidence: The clinical data and its evaluation of a medical device.

4.14 Clinical investigation: Any systematic investigation or study in or on one or more human subjects, undertaken to assess the safety, clinical performance and/or effectiveness of a medical device. When PMCF activity is conducted as clinical investigation involving human participant especially if it is a prospective study designed to collect clinical data beyond routine clinical

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practice investigational brochure is requested. Also, clinical investigation plan is needed in this case.

4.15 Post-market Clinical Follow-up Studies: Studies carried out following marketing authorization intended to answer specific questions (uncertainties) relating to safety, clinical performance and/or effectiveness of a device. This may include PMCF clinical investigation (informed consent is required in this case), Observational clinical follow-up using routine clinical care (consent may or may not be required), retrospective record review and literature review. Complaint analysis and vigilance data.

4.16 Device Registry: An organized system that uses observational study methods to collect defined clinical data under normal conditions of use relating to one or more devices to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure and that serves (a) predetermined scientific, clinical or policy purpose(s).

4.17 Bias is a systematic deviation of an outcome measure from its true value, leading to either an overestimation or underestimation of a treatment's effect. Systematic error can result from flaws in either the method of selecting study participants or in the procedures for gathering relevant exposure and/or disease information.

Studies can be prone to bias. Examples of potential biases in PMCF studies include:

4.171 Selection Bias: Selection bias occurs when the criteria used to include or exclude participants in a study result in a sample that is not representative of the target population. In follow-up studies, this often happens if the patients who enter the long-term observation phase differ systematically from those who do not.

4.172 Information Bias: Also known as **measurement bias**, this occurs when there is a systematic error in how data is collected, measured, or interpreted. This leads to the misclassification of either the "exposure" (the treatment) or the "outcome" (the clinical result).

4.173 Attrition Bias: A specific type of selection bias, **attrition bias** occurs when participants drop out of a longitudinal study (loss to follow-up) in a non-random way.

- **The Risk:** If patients drop out because they are experiencing side effects or because the treatment isn't working, the remaining data will look more favorable than reality.

4.174 Non-response Bias: This happens when the individuals who choose not to participate in a follow-up survey or clinical visit have different characteristics than those who do. It is

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mathematically defined by the difference in the expected value of the sample and the population mean.

4.175 Volunteer Bias: (or **self-selection bias**) occurs when the subjects who volunteer for a follow-up study are fundamentally different from the general population. Typically, volunteers are more health-conscious, have higher education levels, or may be "pro-treatment," which can skew results toward better-than-average outcomes.

4.176 Recall Bias: Common in retrospective follow-up studies, **recall bias** occurs when participants do not remember past events accurately or omit details.

- **Example:** A patient who experienced "success" might forget minor side effects, while a patient who suffered a complication might scrutinize and over-report every minor symptom they experienced during the trial.

4.177 Interviewer Bias: arises when the person collecting the data (the clinician or researcher) consciously or unconsciously influences the participant's responses. This can happen through leading questions, tone of voice, or by "weighting" the recording of symptoms based on their knowledge of which treatment the patient received

4.178 Confounding is a distortion of the true association between exposure and outcome of interest, and it occurs when the study groups differ with respect to other factors. Studies are often prone to confounding.

5.0 Post Market Clinical Follow Up

Post-Market Clinical Follow-up (PMCF) is a proactive process to collect and analyze clinical data to monitor the safety and performance of a medical device once it is on the market. It involves systematic collection of data to confirm the ongoing clinical benefits, to detect potential risks, and to identify the need for further regulatory actions such as design changes or labeling updates, etc. The guideline should consider the use of follow-up schedule for ongoing subjects and additional planned subjects in the PMCF study

While clinical evidence is a vital component of the premarket conformity assessment to prove compliance with the Essential Principles, it's important to recognize that the clinical data available during the premarket phase may have limitations. These limitations could stem from factors like the duration of premarket clinical trials, the number of participants and study locations, the similarity of participants and investigators, as well as how well variables are controlled in the trial

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setting compared to real-world usage. Additionally, for devices built on well-established technologies, it's crucial to understand that clinical data from similar devices may not always be fully applicable to the device in question.

Placing a product on the market is appropriate once it has demonstrated conformity with the relevant Essential Principles, including a positive benefit-risk balance. However, achieving a comprehensive understanding of all potential risks and benefits may not be practical in the premarket phase. Therefore, some uncertainties—such as rare adverse events, long-term safety, or clinical performance—may remain. These should be addressed during the post-market phase through one or more systematic post-market clinical follow-up (PMCF) studies. Importantly, PMCF studies are intended to supplement, not replace, the premarket clinical data necessary for market authorization.

PMCF is a critical component of the Post-Market Surveillance (PMS) system, plays a key role in the overall risk management process and is mandatory under the **NAFDAC Medical Devices, including In Vitro Diagnostics and Related Products, Regulations 2026/123**.

5.1 Conditions for a PMCF:

When considering the overall benefit and risk of a device for marketing authorization, uncertainties may remain regarding the extent of potential benefits and residual risk of the device. PMCF studies can be used to collect additional clinical data to address the remaining uncertainties about a device. Additionally, the risk/benefit analysis summarized should consider the current knowledge of the device.

PMCF studies may also be appropriate to address new concerns arising from post-market adverse event trends, information from literature, signals from adverse event reports, active surveillance programs or other sources.

Uncertainties in the benefit and risk of a device are more likely to exist when dealing with the following scenarios:

5.11 Unanswered questions about long-term safety, clinical performance and/or effectiveness:

Long-term safety, clinical performance and/or effectiveness of a specific aspect of a device may be difficult to assess in a premarket study as it may be necessary to collect data over several years to fully establish the long-term safety, clinical performance and/or effectiveness of the device.

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Additionally, unanswered questions about long-term safety, clinical performance and/or effectiveness of the device may arise from other information, such as:

results of existing clinical investigations.

adverse events identified from post-market surveillance activities.

interaction with other medical products or treatment

5.12 Novel technologies or new intended use.

New technological characteristics, e.g., design, materials, the principles of operation are novel.

Extending/expanding intended use of existing technologies, e.g., new indication or new patient population.

5.13 Higher-risk device and use scenarios: Higher risk anatomical locations; or higher severity of disease/treatment challenges.

5.14 Uncertainties in generalizing clinical investigation results: Generalizing results from study populations to other populations, e.g. from adults to children, from an ethnicity to others. Generalizing results from other jurisdictions to intended jurisdictions.

5.15 Devices approved with clinical data from comparable devices: For devices based on scientifically well-established technologies that have been approved with clinical data from comparable devices and/or preclinical data, it may be appropriate for some of the clinical data collection to occur in the post-market phase.

5.16 Emergence of new information relating to safety, clinical performance and/or effectiveness: When unexpected or unexplained serious adverse events occur after a device is marketed, or if there is a change in the nature (e.g., severity) or an increase in the frequency of expected serious adverse events,

PMCF studies may be conducted to evaluate the potential association of the safety signal and the device.

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5.17 Urgent market access in public health emergencies: In event of public health emergencies (e.g., a pandemic), considerations of benefit and risk of some devices may be different. Expedited market access may be granted with some data generation to occur in the post-market phase.

5.18 Rare anticipated adverse events. Rare anticipated adverse events (e.g. stent thrombosis of the coronary stent) may be difficult to assess in a premarket study but could potentially be identified using large datasets; therefore, it may be necessary to assess the rare adverse events as part of a PMCF study.

5.19 Effectiveness of the mitigation for a known risk: Mitigations may be necessary for known safety risks associated with the use of the device. Confirmation of the adequacy of the mitigation may be evaluated in the post-market phase.

PMCF studies may not be necessary in cases where long-term safety, clinical performance and/or effectiveness are already known from previous use of the device or where other appropriate post-market surveillance activities would provide sufficient data to address any uncertainties. However, the onus is on the manufacturer to provide evidence to justify that PMCF is not necessary.

PMCF is composed of two documents: The PMCF Plan and The PMCF Evaluation Report.

5.2 PMCF Plan

Manufacturers must develop and maintain a PMCF plan that outlines the activities and methods for collecting and analyzing post-market clinical data. The PMCF plan must be integrated into the overall post-market surveillance (PMS) system, which should be designed to proactively address the evolving clinical environment and device performance. The PMCF plan should be submitted with the application for marketing authorization as specified in regulation 123(4) of the NAFDAC Medical devices including In Vitro Diagnostics and Related Products, 2026. The PMCF Plan Template is appendix 2 of this document.

The PMCF plan should be submitted to the pharmacovigilance Directorate by mail to pharmacovigilance@nafdac.gov.ng or by any other means specified by the Agency.

5.21 Components of a PMCF Plan

The PMCF plan must be tailored to the specific device in question and include the following elements:

5.211 Device identification: Clear description of the device(s) and its intended use, including any variations, models, and accessories.

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5.212 Scope of PMCF: Define the objectives, scope, and goals of the PMCF, ensuring alignment with clinical evaluation and post-market surveillance objectives.

5.213 Data sources: Identify the data sources to be used for PMCF, including device registries, clinical trials, patient feedback, literature, real-world evidence, surveys about the use of the device and database analysis.

5.214 Methods of Data Collection:

5.2141 Clinical investigations: Ongoing or new clinical studies to assess the device's safety and performance.

5.142 Registry data: Collecting data from medical device registries, where applicable.

5.143 Surveys and patient-reported outcomes: Collecting feedback from patients and healthcare professionals.

5.144 Other observational data: Post-market studies or cohort analyses.

5.215 Frequency of PMCF activities: Specify how often the manufacturer will review the data and update the PMCF plan, particularly in response to any new risks or findings.

2.216 Clinical performance indicators: Define measurable performance indicators to track the device's clinical outcomes. Information on any other treatments that can influence the clinical outcome that was not considered.

2.217 Roles and responsibilities: Designate key personnel responsible for the implementation of the PMCF plan, including monitoring, data analysis, and reporting.

5.3 Risk-Based Approach

5.31 PMCF activities should be prioritized based on the device's risk classification, potential hazards, Previous clinical/performance data gaps, observed trends from complaints, incidents, or vigilance and the nature of its use.

5.32 High-risk devices should undergo more frequent and comprehensive PMCF activities, including clinical investigations. Low-risk devices may be subject to less intensive follow-up measures, but ongoing monitoring is still required.

5.4 Elements of a PMCF Study

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PMCF studies are performed on a device within its intended use/purpose(s) according to the instructions for use. It is important to note that PMCF studies must be conducted according to applicable local laws, ethics and regulatory approvals. They should follow appropriate guidance and standards such as **Good Clinical Practice (GCP) & Good Laboratory Practice (GLP)**. The PMCF study should take into consideration whether the activity is an interventional PMCF or non-interventional PMCF. For non-interventional PMCF activities, such as literature review, complaint trend analysis, registry review, retrospective review of anonymized data, and post-marketing data analysis, requirements for interventional clinical investigations—such as clinical investigation authorization, investigational brochure, and full clinical investigation plan—may not apply. However, ethical review, data protection requirements, and NAFDAC notification or authorization may still be required depending on the nature of the activity, the data source, whether identifiable patient data are used, and whether the activity goes beyond routine clinical practice.

Additionally, they must comply with the requirements of:

- ISO 14155 for devices
- Nigerian Data Protection Act (NDPA), 2023 compliance for patient data

The elements of a PMCF study should include:

- Clearly stated objective(s) (details see 3.1).
- Scientifically sound study design with appropriate rationale and statistical analytical methods, which may be descriptive or inferential, summarized in a study plan (details see 6.32).
- Implementation of the study according to the study design, an interpretation of the results and appropriate conclusion(s) (details see 6.33).

5.41 The Objective(s) of PMCF Studies

The primary objectives of PMCF are:

- **Monitoring device performance and safety:** To ensure that the device continues to perform as intended and does not pose new or previously unknown risks after being introduced to the market.
- **Identification of potential hazards and device failures:** To detect early signals of problems that may affect patient safety or device functionality.

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- **Post-market clinical data generation:** To collect and analyze real-world data that can inform further clinical evaluations, regulatory updates, or product improvements.
- **Continuous benefit-risk assessment:** To ensure that the benefit-risk ratio remains favorable throughout the lifecycle of the device.

The objective(s) of the study should be stated clearly and should address one or more remaining or newly developed uncertainties related to the safety, clinical performance and/or effectiveness of the device. A formal hypothesis should be clearly expressed, with the acknowledgement that formal statistical hypothesis testing may not be necessary in some circumstances, e.g. descriptive studies.

5.42 The Design of PMCF Studies

The study should be designed to address the objective(s) of the study. The PMCF study can take several forms, for example:

1. continuing to follow up patients enrolled in premarket investigations
2. a new post-market clinical investigation
3. a review of data derived from a device registry; or
4. a review of relevant retrospective data from patients previously exposed to the device.

An appropriate study design should be scientifically sound to allow for valid conclusions to be drawn. Several factors should be considered during the design of the study, for example:

- Study settings should be clearly described, including the locations and selection of sites and investigators.
- The study population should be clearly defined by providing inclusion and exclusion criteria, and the sources and methods for the selection of subjects.
- The control/comparison groups (if any) should be clearly defined and justified.
- Sample size should be clearly stated and justified, if applicable.
- All variables/indicators/measures should be clearly defined, including outcomes/endpoints, adverse events, risk factors, confounding factors, and effect modifiers. For some PMCF studies, data is obtained from routine use in clinical practice. The sources of data and methods of assessment should be provided.
- The type and duration of patient follow-up and measures to minimize losses.
- Potential sources of bias should be identified and evaluated; and related control methods should be discussed (potential biases in PMCF studies and controlling methods are described in Appendix 1 (informative)).
- Statistical analytical methods, which may be descriptive or inferential, should be clearly described. Appropriate statistical methods should be considered to examine the impact of

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potential factors, such as confounding factors, effect modification, or missing data on the analysis results.

For PMCF studies that involve a treatment assignment, including randomization, the approach and procedures used for assigning treatment should be clearly described. If a case-control or cohort design is used, the exposure classification, choice of cases and controls, as applicable, should be described.

5.43 The Implementation of PMCF Studies

The study should be executed according to the PMCF study plan, and the collected data should be analyzed and interpreted to draw the right conclusion.

5.431 PMCF Methodology

The following methodologies should be used to ensure effective PMCF:

- a. **Post-Market Clinical Studies:** For devices that pose higher risk, implants, novel devices or devices that have limited clinical data prior to market introduction, manufacturers may need to conduct specific post-market clinical studies. These could be observational or randomized clinical trials.
- b. **Surveillance via Registries:** For devices with widespread use, manufacturers should contribute to or create a post-market registry to collect long-term safety and performance data. For example, use of national or hospital-based registries
- c. **Surveys and Feedback Mechanisms:** Collecting feedback from healthcare professionals, patients, and users through surveys using structured questionnaires to clinicians or labs, complaint monitoring, and device usage tracking.
- d. **Literature Monitoring:** Regularly reviewing and analyzing published literature to identify any emerging issues, clinical trends, or new indications for the device as supplementary, not primary source of data.
- e. **Incident Reporting:** Monitoring and analyzing adverse events, device failures, and other incidents through established regulatory reporting systems (e.g., NAFDAC Medical devices Adverse Events Data Base, EUDAMED, FDA MAUDE, DAEN, etc.).

5.432 Factors that should be considered during the implementation of the study plan should include:

1. **Data collection:** validated measurement methods/instruments should be utilized, and heterogeneity of data should be considered and controlled; All data on study participants should be handled confidentially. Appropriate technical measures including secure

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electronic storage, user access control, password protection, regular data backups, audit trails and a secure data disposal procedure should be in place to protect collected data.

2. **Quality control:** investigator selection, training, inspection and supervision of the study should be performed to ensure quality.
3. **Data Analysis and interpretation:** Manufacturers should employ robust methods for data analysis, ensuring that the collected post-market data is interpreted correctly. This includes:
 - **Trend analysis:** Identifying patterns or trends in adverse events, device performance, or clinical outcomes that may indicate emerging risks or safety concerns.
 - **Benefit-risk assessment:** Continuously reassessing the benefit-risk balance based on new clinical evidence, ensuring that benefits continue to outweigh risks.
 - **Comparative analysis:** Comparing the device's real-world performance against pre-market clinical studies and other similar devices to assess whether its real-world use matches expectations.

6.0 Reporting and Documentation

A study report should be developed to demonstrate if conclusions relate back to original objective(s) and hypothesis/hypotheses. Manufacturers should document findings in a **PMCF Evaluation Report (see appendix 2)** containing:

- Summary of study methods and results
- Safety and performance outcomes
- Statistical analysis and data interpretation
- Impact on clinical evaluation and risk management
- Recommendations for label updates, design changes, or further investigations

This report should feed into the:

- **Clinical Evaluation Report (CER)** for devices
- **Periodic Safety Update Report (PSUR)**

Additionally, if any safety or performance issues were identified, the manufacturer should develop and implement corrective or preventive actions to address them.

7.0 Submission and Review

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In line with the provisions of the NAFDAC Medical Devices Including In Vitro Diagnostics and Related Products Regulation, 2026/123:

- The PMCF plan and reports should be part of Technical **Documentation**.
- These documents should be reviewed by **the expert advisory committee** during conformity assessments and prior to granting marketing authorization
- Updates should be made available for regulatory inspections or audits.

8.0 PMCF Updates and Revisions

The PMCF plan and activities should be reviewed and revised periodically. Updates should be made when:

- New clinical data or adverse event reports suggest that the device's performance or safety profile has changed.
- There are regulatory or policy changes that affect PMCF requirements.
- New indications, contraindications, or technological advancements impact device use.
- Changes in the device's manufacturing process or post-market surveillance activities necessitate further follow-up.

9.0 Compliance and Auditing

Manufacturers should ensure that PMCF activities are performed in compliance with all applicable regulatory requirements and standards, including:

- Regular internal and external audits to verify the effectiveness of PMCF activities.
- Documentation of compliance with the requirements for PMCF in clinical evaluation and post-market surveillance reports.
- Continuous improvement based on audit findings and new regulatory requirements.

Failure to comply with the PMCF requirements may result in regulatory action consistent with the Agency medical device regulation, which may include a request for corrective action, additional post-market studies, suspension or variation of product registration or other enforcement measures as appropriate.

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10.0 The Relevance of Information from PMCF Studies

The data and conclusions derived from the PMCF studies are part of the post-market surveillance program and used as input in the clinical evaluation and risk management process. This may result in the need to reassess whether the device continues to comply with the Essential Principles. Such assessment may result in corrective or preventive actions, for example:

- ❖ changes to the labelling/instructions for use,
- ❖ changes to manufacturing processes,
- ❖ changes to the device design,
- ❖ public health notifications, or
- ❖ product removal/withdrawal.

In addition, clinical data/evidence generated from PMCF studies can be used:

- as part of premarket clinical evidence, or supplementary data for next- generation or similar technologies when applying for marketing authorization.
- to develop objective performance criteria and performance goals
- to form control/comparison groups

11.0. Conclusion

Effective post-market clinical follow-up is an essential part of maintaining the safety, performance, and clinical benefits of medical devices after they have been introduced to the market. These guidelines aim to support manufacturers in developing and implementing comprehensive PMCF plans and activities, ensuring continuous safety and efficacy monitoring.

By following these guidelines, manufacturers will not only meet regulatory requirements but also help to maintain public trust and confidence in the medical devices they produce.

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Appendix 1

(Informative)

Methods of controlling bias and confounding factors in PMCF studies

Examples of methods to control bias and confounding factors in a PMCF study are listed below:

Example of methods to control bias:

- Appropriate selection of study populations and definitive inclusion and exclusion criteria;
- Randomization on group assignment and blinding during data collection and analysis, if applicable;
- Use of validated and consistent survey instruments and measurements;
- Standardized training of study staff;
- Appropriate methods to avoid loss of follow-up, and to improve response rate and validity;
- Selection of appropriate statistical methods, e.g. stratification analysis and sensitivity analysis.

Example methods to control confounding factors:

- Appropriate restriction, randomization, and matching on study populations;
- Multivariate models with adjustment of confounding factors;
- Mantel-Haenszel adjustment on outcomes.

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Appendix 2

Post-Market Clinical Follow-up Plan and Evaluation Report Template

Regulation 123 (1-5) of the NAFDAC medical Devices Including In Vitro Diagnostics and Related products Regulations, 2026 stipulates that:

- (1) The manufacturer shall conduct Post Market Clinical Follow-up, which should run continuously throughout the life cycle of all medical devices marketed in Nigeria regardless of risk classification.
- (2) Findings from the PMCF shall be incorporated into the PSUR
- (3) The design of PMCF studies and surveys should be documented in a PMCF Plan and results must be collated in a PMCF Report that forms an important input to the Clinical Evaluation Report (CER) for the device.
- (4) The PMCF Plan and PMCF Report shall be submitted along with the marketing authorization application
- (5) The PMCF Report shall be in the format and content prescribed by the Agency.

The purpose of these templates is to guide manufacturers in complying with the requirements of the NAFDAC Medical Devices Regulations with respect to the compilation of the PMCF Plan and Evaluation report. This would assist manufacturers in a harmonized and complete presentation of post market clinical data and enable competent authorities to find the information in an organized format.

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Post-Market Clinical Follow-up Plan Template

Post-market clinical follow- up (PMCF) Evaluation Report			
PMCF report number:			
PMCF report date:			
PMCF report version:			
Revision history			
Rev	Revision date	Description of change	Revised by

Section A. Manufacturer contact details
Legal manufacturer name:
Address:
Person responsible for regulatory compliance:
E-mail:
Phone:
Fax:
Authorized representative (if applicable):
Address:
Contact Person:
E-mail:
Phone:
Fax:

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Section B. Medical Device description and specification
Product or trade name:
Model and type:
General description of the device:
Intended purpose ¹
Intended users
Basic UDI-DI
Intended patient population:
Medical condition(s) ² :
Indications:
Contraindications:
Warnings:
List and description of any variants and/or configurations covered by this plan:
List of any accessories covered by this plan:
NAFDAC Registration No: (if available)
Medical devices classification code (if applicable)
Class:
Classification rule:
Expected lifetime ³
Novel product ☐ yes ☐ no
Novel related clinical procedure: ☐ yes ☐ no
Explanation of any novel features:

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1 Intended purpose means the use for which a device is intended according to the data supplied by the manufacturer on the label in the instructions for use or in promotional or sales materials or statements and as specified by the manufacturer in the clinical evaluation

2 It refers to the clinical condition that is to be diagnosed, prevented, monitored, treated, alleviated, compensated for, replaced, modified or controlled by the medical device.

3 The expected lifetime is to be defined during the design input phase by considering the current state of the art for a specific intended use and indication of a device.

Section C. Activities undertaken related to PMCF: : general and specific methods and procedures

In this section it is expected to describe the different activities that will be conducted in post-market, including general and specific methods / procedures to conduct in relation to the product covered by the scope of PMCF, also the aim of each activity described and the rational for the appropriateness of the chosen general and specific methods to achieve those objectives as well as the known limitations of the planned activities for example incomplete follow up, missing data and so on. The timelines of those activities shall also be defined quarterly or at least yearly.

Here are some examples of different activities related to PMCF:

- A manufacturer device registry (specific for the type of device or the group of the medical devices the product belongs to) can be indicated together with a description and a summary of the plan. A pre-specification of what quality and quantity data – based on the risk of the device(s) and the associated accessories – to be collected and analyzed shall be included. Any possible evaluation of suitable national public registries with clinical data on the manufacturer's own device and/or on similar devices could be specified in this section, identifying the expected quantity and quality of data to be gathered and the search protocols to be adopted.
- PMCF studies planned could be indicated in this section, together with a summary of the plan including the design, sample size, the endpoints, the inclusion/exclusion criteria (e.g. extended follow up of patients included in the pre-market clinical investigations, new clinical investigations within the intended use, retrospective studies). In case of implantable devices and class III devices where clinical investigations have not been performed pursuant to Article 61 (4), the PMCF plan shall include post-market studies to confirm the safety and performance of the device.
- Planned Real-world evidence (RWE) analyses could be indicated in this section, together with a summary of the plan including the design, sample size, the endpoints, and analysis

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population. The real-world data (RWD) from which these analyses are based should be of sufficient quality and come from reliable data sources.

- Surveys planned to collect information about the use of the concerned medical device could be described.

Each activity will be developed in a different subsection (e.g. C.1, C.2, ...), and for which the manufacturer will:

- Define where the need of conducting the PMCF activity is coming from (requested by notified body, clinical evaluation report, PMS, risk management report, previous PMCF report, etc.)
- Provide the description of activity, and if it is a general or specific procedure / method.
- Define the aim of this activity:
 - confirming the safety of the medical device
 - confirming the performance of the medical device
 - identifying previously unknown side-effects (related to the procedures or to the medical devices).
 - monitoring the identified side-effects and contraindications
 - identifying and analyzing emergent risks
 - ensuring the continued acceptability of the benefit-risk ratio
 - identifying possible systematic misuse or off-label use of the device
- Describe the different procedures which will be used as part of PMCF:
 - screening of scientific literature and other sources of clinical data
 - post-market studies
 - collecting data in registries
 - survey from health care professionals
 - survey of patients/users
 - review of case reports which may reveal misuse or off-label use
- Describe the rationale for the appropriateness of the chosen methods/procedures, including:
 - the justification for sample size, timescales and endpoints
 - justification for comparator, based on intended purpose and state of the art
 - justification of the study design based on all of the above, and why it is sufficient to ensure representative patient populations and provide for adequate controls on

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sources of bias (an evaluation of the potential sources of bias should form part of this) ○ a statistical justification for the expected quality of outcomes, and justification for why this is satisfactory in light of the residual risks. This an important consideration. For example, retrospective surveys with no justification other than “this should demonstrate the expected quality of evidence that we require,” but without showing a statistical rationale, are not acceptable. ● Provide the timelines of the activity. A detailed and adequately justified time schedule for PMCF activities, such as the analysis of PMCF data and reporting, shall be described.

A summary table of the different PMCF activities foreseen by the manufacturer is provided below:

Number of activity	Description of activity Aim of the activity	Rationale and known	limitations of the activity	Timelines of the activity

Section D. Reference to the relevant parts of the technical documentation

In this section the manufacturer is required to include references to the relevant information from the clinical evaluation report and from the risk management file, which need to be analyzed, followed up, and evaluated in this plan. As an alternative, the manufacturer is required to state that there is no relevant information from the clinical evaluation report and/or from the risk management file to be considered in this plan.

Clinical Evaluation Report (date and version)

Relevant information to be further analyzed and monitored:

-
-
-

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Risk Management File (date and version) Relevant information to be further analyzed and monitored - - - ☐ No relevant information from the clinical evaluation report to be considered in this plan ☐ No relevant information from the risk management file to be considered in this plan
--

Section E. Evaluation of clinical data relating to equivalent or similar devices

The manufacturer shall gather in this section information regarding equivalent / similar devices for which clinical data will be further evaluated and presented in the PMCF report.

Please note that PMCF data intended to demonstrate continuing safety and performance should be sourced from the device under evaluation.

Data from equivalent or similar devices may be used, for example to update the information relating to the state of the art, to identify and further assess relevant safety outcomes etc.

The selected devices shall be consistent throughout the technical documentation. Indicate whether the selected device is demonstrated to be equivalent or is a similar device. For each device listed, a clear reference to the pertinent parts of the CER can be made.

The following items of each equivalent and/or similar devices would be at least provided, in a table format:

Product name of equivalent / similar device	Intended purpose	Intended users	Intended patient population	Medical condition	Indication	Reference to clinical data evaluation in the CER (date,

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						version and location in the text)

Section F. Reference to any applicable common specification(s), harmonized standard(s) or applicable guidance document(s)

Common specification(s) to comply with, if applicable:
(Title, date and version)

Harmonized standards to apply, if applicable
(Title, date and version)

Guidance on PMCF, if applicable
(Title, date and version)

Section G. Estimated date of the PMCF evaluation report

When the manufacturer plans to have the first report. The timelines shall be defined quarterly or at least yearly.

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Appendix 3

Post-market clinical follow-up evaluation report Template

Post-market clinical follow- up (PMCF) plan corresponding to the present evaluation report
PMCF plan number and version:

Post-market clinical follow- up (PMCF) Evaluation Report			
PMCF report number:			
PMCF report date:			
PMCF report version:			
Revision history			
Rev	Revision date	Description of change	Revised by

Section A. Manufacturer contact details
Legal manufacturer name:
Address:
Person responsible for regulatory compliance:
E-mail:
Phone:
Fax:
Authorized representative (if applicable):
Address:

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Contact Person:
E-mail:
Phone:
Fax:

Section B. Medical Device description and specification
Refer to section B from PMCF plan, if there are no changes. If there are changes from PMCF plan, please fill in the different requested fields highlighting those changes
Product or trade name:
Model and type:
General description of the device:
Intended purpose ¹
Intended users
Basic UDI-DI
Intended patient population:
Medical condition(s) ² :
Indications:
Contraindications:
Warnings:
List and description of any variants and/or configurations covered by this plan:
List of any accessories covered by this plan:
NAFDAC Registration No: (if available)
Medical devices classification code (if applicable)

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Class:
Classification rule:
Expected lifetime ³
Novel product ☐ yes ☐ no
Novel related clinical procedure: ☐ yes ☐ no
Explanation of any novel features:

1 Intended purpose means the use for which a device is intended according to the data supplied by the manufacturer on the label in the instructions for use or in promotional or sales materials or statements and as specified by the manufacturer in the clinical evaluation

2 It refers to the clinical condition that is to be diagnosed, prevented, monitored, treated, alleviated, compensated for, replaced, modified or controlled by the medical device.

3 The expected lifetime is to be defined during the design input phase by considering the current state of the art for a specific intended use and indication of a device.

Section C. Activities undertaken related to PMCF: results

In this section the manufacturer shall report all the activities described in section C of the PMCF plan which have been performed, all the collected clinical data obtained from those completed activities, as well as any justification of deviations from the plan.

The discussion shall include the analysis of the findings, whether positive or negative and also the potential impact on the different documents (clinical evaluation report, risk management file, SSCP, etc.) initially reviewed during the conformity assessment.

It is expected for each activity performed, a description in different subsections, related to the type of activities (device registry, PMCF studies, real world evidence, surveys about the use of device, etc.), and for each subsection, a description about the quality of data collected.⁴

Section D. Evaluation of clinical data relating to equivalent or similar devices

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In this section the manufacturer shall report all the clinical data collected relating to an equivalent device or selected similar device(s), provide an analysis and conclusions, and whether changes of the state of the art, or newly identified hazards would have an impact on the devices benefit-risk determination, the clinical evaluation and/or the PMCF plan.

Product name of equivalent / similar device	Results discussed	References used to get the results (publications, part of technical documentation from this equivalent / similar device)
---	-------------------	--

Section E. Impact of the results on the technical documentation

In this section, the manufacturer shall discuss the aggregate results coming from each PMCF activity planned and performed, described in section C, but also results coming from equivalent and/or similar device, described in section D, which are considered to impact the technical documentation and at least the following documents shall be considered:

1. Clinical evaluation report - CER (date and version)

☐ No relevant information from the clinical evaluation report has been considered.

If applicable, it is expected from the manufacturer to describe why some information that might have an impact on the CER has not been considered.

Relevant information analyzed and monitored:

-
-

Analysis of the outcome is to be reported in the updated clinical evaluation report.

2. Risk management file (date and version)

☐ No relevant information from the risk management file has been considered

If applicable, it is expected from the manufacturer to describe why some information that might have an impact on the risk management file has not been considered.

Relevant information analyzed and monitored:

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-

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-
- Analysis outcome to be reported in the risk management file updated:
-
-

Section F. Reference to any common specification(s), harmonized standard(s) or guidance document(s) applied

In this section the manufacturer should point out whether the collected clinical data related to the device in question still confirm adherence to applied common specifications and/or applied harmonized standards, and/or guidance listed in the PMCF plan.

Common Specification(s) applied
(Title, date and version)

Harmonized standard(s) applied
(Title, date and version)

Guidance(s) followed
(Title, date and version)

Section G. Conclusions

This section should present the manufacturer's overall conclusion on the PMCF findings and explain how they relate to the objectives of the PMCF plan. The conclusions should be considered in subsequent clinical evaluations and risk management activities. They should also indicate whether any preventive or corrective actions are required and may inform the next PMCF plan.

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References:

- 1. [hsa.gov.sg/medical devices/adverse events reporting](https://hsa.gov.sg/medical-devices/adverse-events-reporting)**
2. GHTF/FD: 99-7: Adverse Event Reporting Guidance for the Medical Device Manufacturer or its Authorized Representative
3. WHO Model Regulatory Framework for Medical Devices Including in vitro diagnostic medical devices
4. ISO 14155: Clinical investigation of medical devices
5. Section 5, MDCG 2020-5 Clinical Evaluation – Equivalence, A guide for manufacturers and notified bodies.
6. ISO 13485:2016 Quality Management Systems For Medical Devices
7. IMDRFMDCE WG/N57FINAL:2019 Clinical Investigation
8. IMDRF MDCE WG/N65FINAL:2021
9. MDCG 2020-7-Post-market clinical follow-up (PMCF) Plan Template: A guide for manufacturers and notified bodies
10. MDCG 2020-8-Post-market clinical follow-up (PMCF) Evaluation Report Template: A guide for manufacturers and notified bodies
11. Meddev 2.7/1 rev.4